main disadvantages of the study are: (1) it took place over a relatively narrow time frame of 8.5 years which increases the potential for a calendar year bias, and (2) the lower social economic classes are under-represented which may introduce a bias due to the difference in type and way cigarettes are smoked.

D.3.2.1.3. British male physicians. Doll and Peto (1978) published the data shown in Table D-6 based on the information obtained by following the survival of a cohort of approximately 34,000 British male physicians. The smoking histories of each individual in the cohort were obtained by questionnaires at three different points in time. Table D-6 is a subset of the total cohort consisting of subjects who smoked at a nearly constant rate over their smoking lifetime. Due to the quality of the smoking information and pathology confirmation of most of the cases, this study is generally acknowledged to be the most informative available for establishing dose-response relationships. The disadvantages are that the number of observed lung cancer deaths are relatively small (i.e., 215), no women are included in the sample, and information on ex-smokers was never published in a form suitable for analysis. Also, a sample of physicians has a high potential for a sociological bias to be built into it. Ten years of additional observation is available on the cohort that has not yet been published and could be of considerable importance in the establishment of a dose-response model.

TABLE D-6 NUMBER OF LUNG CANCER DEATHS AND PERSON-YEARS OF OBSERVATION FOR BRITISH MALE PHYSICIANS

Mid-point age interval (years)		Average exposure (cigarettes per day)								
		0.0	2.7	6.6	11.3	16.0	20.4	25.4	30.2	38.0
42.5	observed lung cancer deaths	0.0	0.0	0.0	1.0	0.0	1.0	0.0	1.0	0.0
	person-years	17,846.5	1,216.0	2,041.5	3,795.5	4,824.0	7,046.0	2,523.0	1,715.5	892.5
47.5	observed lung cancer deaths	0.0	0.0	0.0	1.0	1.0	1.0	2.0	2.0	0.0
	person-years	15,832.5	1,000.5	1,745.0	3,205.0	3,995.0	6,460.5	2,565.5	2,123.0	1,150.0
52.5	observed lung cancer deaths	0.0	0.0	0.0	2.0	4.0	6.0	3.0	3.0	3.0
	person-years	12,226.0	853.5	1,562.5	2,727.0	3,278.5	5,583.0	2,620.0	2,226.5	1,281.0
57.5	observed lung cancer deaths	2.0	1.0	0.0	1.0	0.0	8.0	5.0	6.0	4.0
	person-years	8,905.5	625.0	1,355.0	2,288.0	2,488.5	4,357.5	2,108.5	1,923.0	1,063.0
62.5	observed lung cancer deaths	0.0	1.0	1.0	1.0	2.0	13.0	4.0	11.0	7.0
	person-years	6,248.0	509.5	1,068.0	1,714.0	1,829.5	2,863.5	1,508.5	1,362.0	826.0
67.5	observed lung cancer deaths	0.0	0.0	1.0	2.0	2.0	12.0	5.0	9.0	9.0
	person-years	4,351.0	392.5	843.5	1,214.0	1,237.0	1,930.0	974.5	763.5	515.0
72.5	observed lung cancer deaths	1.0	1.0	2.0	4.0	4.0	10.0	7.0	2.0	5.0
	person-years	2,723.5	242.0	696.5	862.0	683.5	1,055.0	527.0	317.5	233.0
77.5	observed lung cancer deaths	2.0	0.0	0.0	4.0	5.0	7.0	4.0	2.0	2.0
	person-years	1,772.0	208.5	517.5	547.0	370.5	512.0	209.5	130.0	88.5

Source: Doll and Peto (1978)

D.3.2.1.4. Other data sources. Other sources of information that could prove useful in obtaining information on a dose-response model are Best (1966), Canadian smokers; Bross et al. (1968), individuals who switched to filter cigarettes; Cederlof et al. (1975), a national probability sample of Swedish subjects; Graham and Levin (1971), individuals who stopped smoking; Hirayama (1977), Japanese smokers; Stevens and Moolgavkar (1984), British males; Lubin et al. (1984), individuals who changed smoking habits; Wald et al. (1988), U.K. smoking statistics; the IARC monograph on the evaluation of the carcinogenic risk of tobacco smoking to humans IARC (1986), general information; and the U.S. Public Health Service, Smoking and Health Report series for various types of smoking related information.

D.3.2.2. Modeling Approach for Cigarette Smoking Data--Various investigators, such as Doll and Peto (1978), Thorslund and Charnley (1987), Brown and Chu (1987), Gaffney and Altshuler (1988), Darby and Pike (1988), Freedman and Navidi (1989), and Moolgavkar et al. (1989), were successful in fitting various forms of multi-stage type models to the British physicians data. Modeling attempts using the AWV and ACS data have been less successful. Freedman and Navidi (1989) could not obtain adequate fits using standard multi-stage models to the AWV and ACS data sets when information on ex-smokers was included. The reasons for this inability could be either deficiencies in the multi-stage model (hypothesis put forth by the authors) or some unknown bias in the data that distorts the true dose-response relationship. To clarify the situation other modeling approaches should be attempted.

Probably the most successful approach for mathematically modeling cigarette smoking data was put forth by Moolgavkar et al. (1989). This is the only attempt to date to incorporate a promotional component of cigarette smoke into a dose-response model. Using Moolgavkar's basic model and the additional simplifying robust assumptions that:

- the number of stem (target) cells are constant over time,
- the ratio S of unit exposure induced to background cell transition rates are equal for the two cellular transitions (i.e., normal stem to preneoplastic and preneoplastic to neoplastic), and
- the growth rate of preneoplastic cells is a function, G(x), of the number of cigarettes smoked per day,

the age-specific lung cancer rate of an individual at age t who has smoked x cigarettes per day since age t_0 can be expressed as:

$$h(x,t) = \frac{A}{G(x)}(1+Sx)^2\{\exp[G(x)(t-t_0)]-1\} + \frac{A}{G(0)}(1+Sx)\exp[G(x)(t-t_0)]\{\exp[G(0)t_0]-1\}$$

where A is the product of the background transition rates, $G(x) = G(0)[1+(R-1)M(x)]$ with $R = G(\infty)/G(0)$ being the maximum relative growth rate increase that can be induced by cigarettes and M(x) is a still to be specified function that defines the fraction of the maximum growth rate increase that is induced with x cigarettes per day. In the model employed by Moolgavkar, the simplifying assumption $G(x) = G(0) + \Delta x$ was made. While this assumed relationship may be appropriate at low doses, it very likely results in a distortion of the effect for heavy smokers.

It is proposed that the Moolgavkar (i.e., two-stage) model parameter estimates be obtained by simultaneously using multiple epidemiological-smoking-lung cancer data sets and the following modifications and extensions of the above basic model:

- Moolgavkar assumed that the time from the development of a neoplastic cell until death due to a lung cancer was a constant 3.5 years for each of the lung cancer deaths. As an alternative this length of time will be estimated by maximum likelihood methods assuming:

  1. it is a constant unknown value for all lung cancer deaths, and
  2. it is a random variable with an integer gamma probability distribution.

- Alternative-specific forms for G(x) will be specified based on various assumptions of how binding of smoking product agents with preneoplastic cells induce promotion.....

- An adjustment will be made for the difference between British and American cigarettes and British and American smoking habits.
- An investigation will be made of the hypothesis that G(0) may be different pre- and post-exposure to accommodate the observation of rapidly falling age-specific rates post cessation of smoking.

The largest information data base possible will be used in fitting the different variations of the model. An illustration of how one of the parameters in the model, G(0), could be estimated is given below.

Hammond (1966) pooled the ACS lung cancer mortality data for men and women nonsmokers and obtained age-specific death rates for five-year age intervals. This information is displayed in Table D-7. The justification given by Hammond (1966) for pooling the data was the inability to reject the hypothesis of equal rates for the sexes on the basis of a statistical test. Under the assumption of no cigarette smoking, $x=0$, so the previously described age-specific rates for the two-stage model has the reduced form:

$$h(0,t) = \frac{A}{G(0)}\{\exp[G(0)t]-1\}$$

Assuming that the number of lung cancer cases out of the number of person years of observation was an independent binomial random variable for each age class, maximum likelihood estimates were obtained for the unknown parameters A and G(0) in the above model. The adequate fit of the model is displayed in Table D-7 and Figure D-1.

It is reasonable to assume that the parameter G(0) is human population independent and, perhaps, even species independent taken on a lifetime equivalent time scale. However, the value A would most likely be dependent on the environmental conditions an individual is living under. Therefore, different values for U.S. and British populations should be estimated.

TABLE D-7. LUNG CANCER DEATH RATES PER 100,000 PERSON-YEARS AND OBSERVED AND PREDICTED NUMBER OF LUNG CANCER DEATHS AMONG MEN AND WOMEN WHO NEVER SMOKED REGULARLY

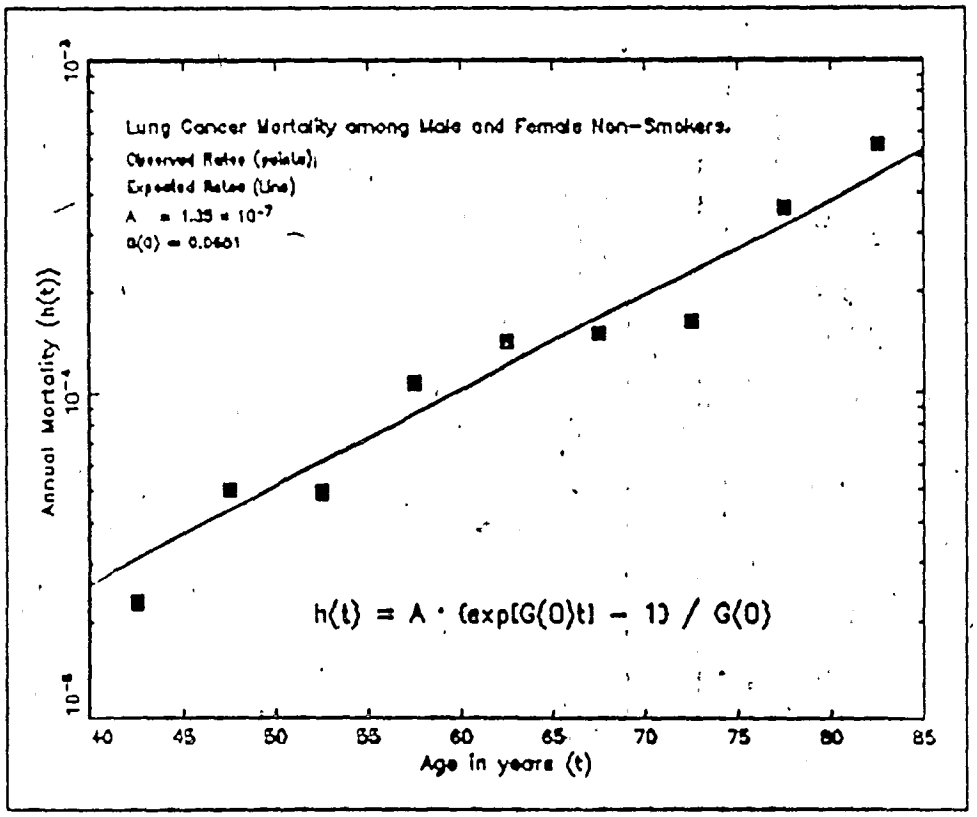
Age group L to L+5	Combined men and women			Population size N (person-years)
	Number of lung cancer deaths n		Death rate dr	
	Observed	Predicted		
40-44	4	5.40	2.3	173,913
45-49	16	14.01	5.0	320,000
50-54	16	20.05	4.9	326,531
55-59	30	24.52	10.5	285,714
60-64	32	27.53	13.9	230,216
65-69	26	29.43	14.7	176,871
70-74	18	25.84	16.1	111,801
75-79	21	18.82	35.8	58,659
80-84	14	11.41	54.6	25,641
Total	177	----		

Source: Hammond (1966)/ACS Study

$N = \frac{nx10^5}{dr}$

calculated from data) χ^2, = 7.036 p = 0.425

FIGURE D-1.
GOODNESS-OF-FIT OF TWO-STAGE MODEL TO NON-SMOKERS
AGE-DEPENDENT LUNG CANCER DATA



Source of data. Hammond et al. (1966).

The obvious advantage of the proposed CEA is that it is based on the most extensive body of information concerning the dose-dependent effects of an environmental agent on a human cancer response that exists. The main disadvantages are the complexity of the analysis and the possibility of not establishing a credible ETS equivalency relationship. The latter factor is discussed in the next sections.

D.3.3. Estimation of the Relative Potency of ETS Compared to MS

Previous approaches for establishing ETS/cigarette equivalency (e.g., Darby and Pike, 1988) have made the implicit assumption that the ratio of the potency of emissions to some surrogate measure of internal exposure (e.g., nicotine, cotinine, etc.) is the same for ETS and MS. The large variability in relative potency estimates of complex-PAH mixtures that are displayed in Table D-8 suggests that the implicit assumption of equal potency is suspect.

Several methods can be used to estimate the ETS compared to MS relative potency. The inhalation studies in Syrian golden hamsters where laryngeal carcinomas were elicited from MS (Dontenwill et al., 1973; 1977) and from B[a]P (Thyssen, 1981) can be used to obtain a MS-to-B[a]P relative potency estimate. Dividing this obtained potency value into the ETS-to-B[a]P, the relative potency obtained from the lung implant studies discussed in Section D.1.3.1 would give a relatively potent estimate of ETS to MS. Stanton et al. (1972) conducted a lung implant study using cigarette smoke condensate (CSC). Unfortunately for our present purposes, 3-methylcholanthrene (MCA) was used as the positive control in the experiment so direct comparison with ETS is not possible. However, Grimmer and his colleagues for the most part closely adopted Stanton's experimental protocol for conducting lung implant studies. Thus, a direct pooling of the data in the Stanton and Grimmer experiments could logically be used to obtain a potency estimate. As an alternative, the two-step approach of estimating the potency of

TABLE D-8. RELATIVE POTENCY ESTIMATES OF COMPLEX MIXTURES OF INCOMPLETE COMBUSTION PRODUCTS OF HYDROCARBONS COMPARED TO B[a]P

Complex PAH exposure	Direct bioassay estimate* of relative potency
Coal Flue Gas Condensate	0.05444
Gas Engine Condensate	0.02190
Diesel Engine Exhaust	0.00230
Sidestream Cigarette Smoke	0.00302
Coke Oven Emissions	0.03180'

*Lung implant studies
'Skin painting

CSC compared to MCA from the Stanton experiment and then establishing the relative potency of MCA compared to B[a]P in another assay system (e.g., subcutaneous injection, skin painting, etc.) could be employed. A final alternative might be to compare the weighted relative potency estimates of the known constituents in the MS and ETS samples that have stable established estimates of their carcinogenic potency compared to B[a]P. One potential list of stable relative potency estimates developed by Thorslund (1990) is shown in Table D-9.

The last piece of information required to obtain an ETS risk model based upon the CEA is a deposition ratio estimate between MS via active smoking and ETS under normal inhalation conditions. One promising approach of using B[a]P-DNA-adducts and other endpoints as biomarkers is discussed in the next section.

D.3.4. Deposition Differences of Chemicals from Cigarette Smoke in Smokers and Nonsmokers

To obtain an equivalency relationship between MS and ETS, both potency and deliverable dose conversion factors are needed in order to use the MS-lung cancer data as a surrogate for lung cancer induced by ETS.

TABLE D-9. RELATIVE POTENCY ESTIMATES OF AGENTS COMPARED TO B[a]P

Agent	Relative potency	Source of estimate
Anthracene	0.00000	IARC adequately studied, no indication of carcinogenic effect category
Fluoranthene	0.00000	
Pyrene	0.00000	
Benzo[b]fluoranthene	0.12277	Deutsch-Wenzel et al. (1983) (Grimmer's group) lung implant data Thorslund (1990) estimates
Benzo[k]fluoranthene	0.05322	
Benzo[j]fluoranthene	0.05232	
Benzo[e]pyrene	0.00704	
Benzo[a]pyrene	1.00000	
Indeno Pyrene	0.27800	
Benzo[ghi]perylene	0.02124	
Anthanthrene	0.31598	

Under the assumption that the PAHs possess most of the carcinogenic potency in MS and ETS, the deliverable target dose can be estimated by directly measuring the number of DNA adducts formed in people smoking different numbers of cigarettes per day and in people who are nonsmokers in the presence of smokers with different frequencies of smoking.

Specific adducts, such as the DNA 7,8-diol-9,10-epoxide of B[a]P which is present in both MS and ETS, can be detected using sensitive immunoassays or postlabelling DNA techniques (Shamsuddin et al., 1985; Randerath et al., 1986). Differences in adduct formation between smokers and nonsmokers varied depending on the experiment but was as high as 400-fold when DNA from oral mucosa was analyzed using the postlabelling technique. Hemoglobin adducts as markers of genotoxicity have been analyzed in smokers and nonsmokers where smokers had about a 7-fold greater number of adducts than nonsmokers.

Indirect measures of dose between smokers and nonsmokers may also be available in which gene mutations can be measured in peripheral leukocytes at the Hypoxanthine phosphoribosyl transferase locus as well as other loci. In fact, such a test could conceivably be used directly to obtain a cigarette equivalence estimate without making potency difference adjustments. Other genetic damage tests, such as chromosomal aberrations and sister chromatid exchanges, may also be useful in determining deliverable target dose information for smokers and nonsmokers exposed to ETS.

To obtain an equivalency relationship of deliverable dose between smokers and nonsmokers, a thorough review of the literature for articles that show dose-response relationships between MS/ETS and DNA adducts, protein adducts, and gene mutations should be conducted and the most appropriate endpoints selected for use in the equivalency estimate. The main advantage of the approach is the high suspected correlation of the endpoint with the cancer response. The main disadvantage is the discounting of potential agents that act exclusively as promoters.

D.4. DIRECT APPROACH

The most straightforward approach for estimating ETS lung cancer risk is to estimate ETS exposure in a suitable cohort and follow the resulting mortality pattern over time. As of yet, no directly measured ETS exposure data exist on a cohort. The ideal in this regard would be personal monitoring data obtained from nonsmokers for an agent such as cotinine which is closely and uniquely associated with cigarette smoke. In this application, the use of cotinine is appropriate as long as it is linearly related to total ETS air levels. In lieu of such information, investigators have attempted to obtain surrogate measures of ETS. One such measure is the number of cigarettes smoked per day by the spouses of nonsmoking individuals. The quality of such a surrogate measurement depends upon: (1) the extent that nonsmokers are exposed to

smokers other than their spouses, (2) the consistency within the cohort of the husbands' and wives' spatial and time closeness, and (3) the consistency within the cohort of the fraction of the total cigarettes that are smoked by the spouse in the home. Due to sociological factors regarding a woman's place in Japan, the homogeneity of the Japanese society, and the small, close living arrangements of Japanese couples, probably the best surrogate measure of ETS exposure available is the number of cigarettes smoked per day by the husbands of Japanese women. The person-years of observation and the number of lung cancer deaths for Japanese women classified in regard to their husband's age and smoking habits obtained in the prospective study conducted by Hirayama (1984) is displayed in Table D-10. Under the assumption that all the excess lung cancer risk in Japanese women was due to husband-produced ETS exposure in the home, crude risk models can be generated from the information supplied in Table D-10. Better estimates could be obtained if information such as the length of marriage, wife's age, age husband started smoking, and smoking habits of wife's parents were available for individual cohort members. A fair amount of such information has been generated by Hirayama (1984) but presently is not reported in the open literature. Gaining access to the data could prove valuable.

TABLE D-10. LUNG CANCER MORTALITY IN JAPANESE WOMEN BY HUSBAND'S AGE GROUP AND SMOKING HABITS (PATIENT HERSELF A NON-SMOKER)*

Husband's age group	Husband's smoking habit											
	Non-smoker		Ex-smoker		1-14/day		15-19/day		20+/day		Total	
40-49	4	6,229	1	1,255	8	8,621	6	5,158	16	10,764	35	32,027
50-59	10	7,791	3	1,922	20	9,668	8	4,052	24	9,820	65	33,253
60-69	18	7,120	11	2,687	28	7,243	9	2,513	23	4,651	89	24,214
70-79	5	755	2	348	2	612	1	105	1	226	11	2,046
Total	37	21,895	17	6,212	58	26,144	24	11,828	64	25,461	200	91,540

*Number of lung cancer deaths out of number of wives in the same cross classification cell.
Source: Hirayama (1984).

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